EXHIBIT D

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
	2:12-md-02327
THIS DOCUMENT RELATES TO:	**HON. JOSEPH R. GOODWIN**
Stephanie Booher, et al. v. Ethicon, Inc.., et al	

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Bern Ripka Law Firm to give medical opinions related to Stephanie Booher. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae is attached to this report as **Ex. A**. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical and scientific certainty. My reliance list is attached as **Ex. B**.I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these devices. Further, I am familiar with non-mesh options for the

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treatment of stress urinary incontinence including autologous tissue based slings, biological graft-based slings, and periurethral bulking procedures. I have attended training provided by Ethicon, Inc. including training on TVT devices. Additionally, I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon a review of her medical records, and knowledge of her prior medical history.

Medical records and depositions reviewed include:

- Dr. Dennis Samuel
- Sapling Grove Surgery Center records
- Wellmont Holsten Valley Medical Center
- Season Women's Health-Bristol
- Deposition, Stephanie Booher

Clinical History

- On October 12, 2004, Mrs. Booher presented as a 28 year old G2P2 female with stress urinary incontinence (SUI). Her past medical history was remarkable for low back pain and intermittent pelvic pain which apparently worsened with menses. Of note, she was sexually active with no complaints of dyspareunia.

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- On October 19, 2004, Dr. Samuel performed urodynamics on Mrs. Booher which demonstrated "probable" SUI.

- On November 11, 2004, Dr. Samuel discussed the TVT surgery with Mrs. Booher, and she decided to proceed with surgery.

- On November 18, 2004, Mrs. Booher underwent placement of a retropubic TVT. The procedure was performed using conscious sedation and the sling was set in a tension-free fashion using a right angle as a spacer.

- On December 16th, 2004, she saw Dr. Samuel and seemed to be doing well, having no incontinence or vaginal bleeding.

- On January 8, 2007, Mrs. Booher saw Dr. Samuel with chronic low back pain that was attributed to either a discogenic or gynecologic issue. Her pelvic exam was unremarkable.

- On August 3, 2009, due to pelvic pain, Dr. Beckner performed diagnostic laparoscopy that was unrevealing. Subsequently, Mrs. Booher was provided a trial of Depo-Lupron to see if controlling her adenomyosis might result in improvement of her pelvic pain. This therapy resulted in improvement of her pelvic pain and she was counselled towards hysterectomy.

- On March 11, 2008 she saw Dr. Samuel for her annual Gyn exam. Dr. Samuel memorialized that she had no complaints and she had an otherwise normal pelvic exam.

- On November 30, 2009, Mrs. Booher underwent total abdominal hysterectomy and bilateral salpingo-oophorectmy due to chronic pelvic pain. She was discharged home on December 3, 2009 and was prescribed Estradiol 1 mg daily.

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Methodology

My general opinions based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk-benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion the IFU for the TVT in 2004 was not sufficient to enable informed consent from the patient. The TVT IFU provided:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.

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- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction (i.e. too much tension) applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina, peri-vaginal, and those tissues adjacent to the mesh persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation

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today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. It is my opinion that a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

In 2004, alternative successful and safer sling procedures were available, including autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Mrs. Booher was unable to receive proper informed consent relating to this safer alternative because of the lack of information in the TVT IFU inherent to the risks of using synthetic mesh. As such, Dr. Samuel was unable to warn Mrs. Booher of the subsequent complications she has suffered from.

Case Specific Opinion No. 1

Mrs. Berry's developed vaginal pain and dyspareunia as a result of her TVT device. Recognized causes of dyspareunia following synthetic sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury; (7) lichen sclerosis; (8) vaginal tissue atrophy; and (9) pelvic floor dysfunction.

Of interest, there is no documentation of dyspareunia within the medical records. There is an extensive and repetitive history of pelvic and lower back pain that is influenced by Mrs. Booher's menstrual cycle and appears to be ameliorated by treatment with Depo-Lupron. Within Mrs. Booher's deposition, however, there is clear reference to severe and persistent dyspareunia that starts 4 to 6 months following sling surgery. She rated the pain as 6 ½-7/10 soon after her surgery and 4-5/10 as of her deposition performed on May 10, 2016. She described the pain as "pain and pressure inside. Like down low" and is now sexually active every 4 to 6 weeks. She also has pelvic pain not related to intercourse.

I am able to rule out erosion; paraurethral banding; infection and inflammation; lichen sclerosis; and vaginal tissue atrophy potential causes of Mrs. Booher's vaginal pain and dyspareunia because I have not seen paraurethral banding documented. Additionally, I am not able to rule in neuromuscular injury or pelvic floor dysfunction as a causative factor having not seen this in the

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medical records either. The one plausible cause for Mrs. Booher's pelvic pain and dyspareunia, vaginal scarring with reduced elasticity, is also not seen within the medical records.

In summary, Mrs. Booher's dyspareunia has no clear etiology based on the current medical records I have reviewed. In as much as her deposition makes these claims, the only way to corroborate these complaints would be to conduct or review an independent medical examination that might otherwise shed light on the etiology and underlying issues explaining her pelvic pain and dyspareunia

Case Specific Opinion No. 2

Ms. Booher's future prognosis as it relates to her pelvic pain and dyspareunia is guarded. Mrs. Booher is a relatively young woman, 40 years old at the time of this report. She continues to have pelvic pain and dyspareunia presently. Under the presumption that her dyspareunia and vaginal pain are caused by the TVT sling implanted in her by Dr. Samuel, she will likely have some degree of vaginal pain and dyspareunia for the rest of her life . Because she has residual pelvic mesh still inside of her body, she will continue to suffer from pelvic pain and dyspareunia. Even if she were to have all of her mesh removed, the surgery require to execute this procedure is extensive, complicated, and almost exclusively performed in tertiary academic centers. Moreover, I anticipate that if heroic surgery were performed to remove all of her mesh that she would develop further scarring and fibrosis inherent to this procedure.

These represent my current opinions in this case. As any additional material becomes available, I reserve the right to modify or add to this opinion.
Dated this the 22nd day of July, 2016

Sincerely,

Konstantin Walmsley, M.D.